K082127

AUG 27 2008

4. 510(k) Summary

This summary of safety and effectiveness is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.87.

Establishment Registration Number:	2021898
Address of Manufacturer:	Medtronic Neurosurgery 125 Cremona Drive Goleta CA, 93117 (805) 571-8445 Fax: (805) 571-8480
Contact Person:	Jeffrey Henderson
Date:	July 28, 2008
Trade or Proprietary Name:	PS Medical® Strata® NSC Burr Hole Valves and Shunt Assemblies
Common Usual or Classification Name:	Central nervous system fluid shunt and components (882.5550)
Predicate Device Identification:	• Medtronic PS Medical Strata NSC Valve and Shunt Assemblies (K038850) • Medtronic PS Medical Strata II Valves and Shunt Assemblies with and without BioGlide (K042465) • CSF-Flow Control Valve, Burr Hole (K831678)

Description:

The PS Medical® Strata® NSC Burr Hole Valve is an adjustable non-siphon control valve. The valve is manufactured of silicone elastomer and polypropylene. The valve is used as a shunt component. The adjustable valve is designed for non-invasive pressure flow adjustment.

Intended Use:

- The Strata NSC Burr Hole Valves and Shunt Assemblies are shunt components designed to provide continued cerebrospinal fluid (CSF) flow from the ventricles of the brain into the right atrium of the heart or the peritoneal cavity. The Strata NSC Burr Hole Valve allows the physician to non-invasively adjust valve pressure/performance level pre- and post-implantation by using a special magnetic adjustment tool without the need for radiographic confirmation in order to address changing patient needs.

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Intended Use of Predicate Device(s):

- The Strata NSC Valves and Shunt Assemblies are shunt components designed to provide continued cerebrospinal fluid (CSF) flow from the ventricles of the brain into the right atrium of the heart or the peritoneal cavity. The Strata NSC Valve allows the physician to non-invasively adjust valve pressure/performance level pre- and post-implantation by using a special magnetic adjustment tool without the need for radiographic confirmation in order to address changing patient needs.
- The Strata II Valves and Shunt Assemblies are shunt components designed to provide continued cerebrospinal fluid (CSF) flow from the ventricles of the brain into the right atrium of the heart or the peritoneal cavity. The Strata II Valve allows the physician to non-invasively adjust valve pressure/performance level pre- and post-implantation by using a special magnetic adjustment tool without the need for radiographic confirmation in order to address changing patient needs.
- The CSF-Flow Control Burr Hole Valve is a shunt component designed to provide continued cerebrospinal fluid (CSF) flow from the ventricles of the brain into the right atrium of the heart or the peritoneal cavity.

Technological Comparison:

Medtronic Neurosurgery submits that the Strata NSC Burr Hole Valves and Shunt Assemblies included in this submission are manufactured of identical materials, and have the same intended use and fundamental scientific technology as the previously reviewed and cleared:

- Medtronic PS Medical Strata NSC Valve and Shunt Assemblies (K038850)
- Medtronic PS Medical Strata II Valves and Shunt Assemblies with and without BioGlide (K042465)
- PS Medical CSF Flow Control Valve, Burr Hole (K831678).

Based upon the summary above, Medtronic Neurosurgery has determined that the proposed Strata NSC Burr Hole Valves and Shunt Assemblies are safe and effective and substantially equivalent to the predicate and currently marketed devices.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 7 2008

Medtronic Neurosurgery
% Mr. Jeffrey Henderson
VP, Quality & Regulatory Affairs
125 Cremona Drive
Goleta, California 93117

Re: K082127
Trade/Device Name: PS Medical® Strata® NSC Burr Hole Valves and Shunt Assemblies
Regulation Number: 21 CFR 882.5550
Regulation Name: Central nervous system fluid shunt and components
Regulatory Class: II
Product Code: JXG
Dated: July 28, 2008
Received: July 29, 2008

Dear Mr. Henderson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

II. Statement of Indications for Use

510(k) Number (if known): K082127

Device Name: PS Medical® Strata® NSC Burr Hole Valves and Shunt Assemblies

Indications for Use:

The Strata NSC Burr Hole Valves and Shunt Assemblies are shunt components designed to provide continued cerebrospinal fluid (CSF) flow from the ventricles of the brain into the right atrium of the heart or the peritoneal cavity. The Strata NSC Burr Hole Valve allows the physician to non-invasively adjust the pressure/ flow performance level pre- and post-implantation without the need for radiographic confirmation in order to address changing patient needs.

Prescription Use (Part 21 CFR 801 Subpart D)	✓	AND/OR	Over-The-Counter Use (21 CFR 801 Subpart C)	

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K082127